Proposed Registration Decision PRD2016-24

Canola Oil

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Overview

Proposed Registration Decision for Canola Oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Vegol TGAI and Vegol Ready-to-spray, Vegol Commercial and Vegol Concentrate, containing the technical grade active ingredient canola oil, to control a variety of insect and mite pests, as well as to suppress powdery mildew, on many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse, as well as on *Cannabis* (marihuana) produced commercially indoors for medical purposes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of canola oil and Vegol TGAI.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on canola oil, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on canola oil, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Canola Oil?

Canola oil is the active ingredient in Vegol Commercial, Vegol Ready-to-Spray, and Vegol Concentrate. This active ingredient has properties of an insecticide, miticide, and fungicide since it controls a variety of insects and mites and suppresses powdery mildew on many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse, as well as on *Cannabis* (marihuana) produced commercially indoors for medical purposes. As an insecticide/miticide, canola oil acts predominately through suffocation, while as a fungicide, it creates a physical barrier to prevent plant infection by fungi.

Health Considerations

Can Approved Uses of Canola Oil Affect Human Health?

Canola oil is unlikely to affect human health when used according to label directions.

Exposure to canola oil may occur when handling and applying the end-use products Vegol Commercial, Vegol Ready-to-Spray and Vegol Concentrate. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Canola oil and its associated end-use products are of low toxicity by the oral, dermal and inhalation routes, but are mildly irritating to the skin and minimally irritating to the eye. Based on a review of the available scientific literature, exposure to canola oil is not expected to have any short-or long-term health effects.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is not of concern based on the low toxicity of canola oil in addition to its long history of use as a food.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

It is expected that the uses of canola oil in Canada on food crops will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops.

Minimal exposure to canola oil is expected in drinking water and thus, no risk due to exposure from drinking water is anticipated.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Canola oil is proposed for use on indoor plantscapes, greenhouse and agricultural field crops, and around the home on garden and houseplants. The application directions on the product labels include statements to minimize spray drift. Consequently, when the label directions are followed, adults, youths and toddlers should not be exposed to canola oil through drift. Even in the event of exposure, risk to the general population is not a concern due to the low toxicity of canola oil and the history of its use as a food.

Occupational Risks from Handling Canola Oil

Occupational risks are not of concern when canola oil is used according to the proposed label directions, which include protective measures.

The precautionary label statements indicate that contact with eyes, skin and clothing must be avoided. Precautionary and hygiene statements on the label are considered adequate to protect individuals from occupational exposure.

Environmental Considerations

What Happens When Canola Oil Is Introduced Into the Environment?

Canola oil is not expected to pose risks of concern to the environment when used according to label instructions.

Canola oil breaks down rapidly in the environment and is not expected to move downward in soil to groundwater. If canola oil reaches water, it is not expected to mix with water but may remain on the surface of waterbodies, or will stick to plant matter, until it is broken down by bacteria.

Canola oil may pose a risk to some aquatic organisms and spray buffer zones are required to limit exposure of sensitive aquatic habitats from spray drift. Beneficial predatory and parasitic arthropods may also be harmed if contacted by the product spray and, therefore, precautionary label statements for aquatic organisms and beneficial insects will be required. Risks to other non-target organisms from these uses were not identified.

Value Considerations

What Is the Value of Vegol Commercial, Vegol Ready-to-Spray and Vegol Concentrate?

Vegol products, containing canola oil, can be used to control a variety of foliage feeding insects and mites, as well as to suppress powdery mildew, on many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse.

Vegol Commercial is a commercial class product, while Vegol Ready-to-Spray and Vegol Concentrate are domestic class products. They can all be applied to many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse to control mites, scales, whiteflies, aphids, adelgids, psyllids, mealybugs, and/or grape and oak phylloxera. These products may also be applied during the dormant season.

As a fungicide, these products can be applied to suppress powdery mildew on roses, certain ornamental trees, cucurbit vegetables, certain pome and stone fruits, certain berries, grapes, hops, and *Cannabis* (marihuana) produced commercially indoors for medical purposes. Powdery mildew reduces yield in agricultural crops and diminishes the aesthetic value of ornamental plants.

The development of resistance is very unlikely because this is a physical mode of action.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Vegol Ready-to-spray, Vegol Commercial and Vegol Concentrate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To prevent irritation, anyone applying canola oil products must avoid contact with eyes, skin and clothing.

Environment

Spray buffer zones will be required to mitigate potential risk to aquatic invertebrates (that is, field sprayer, 2 m; air blast sprayer, 5 m).

Next Steps

Before making a final registration decision on canola oil, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on canola oil (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Canola Oil

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Canola oil
Function	Suffocant
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Canola oil
2. **Chemical Abstracts Service (CAS)**	Canola oil
CAS number	120962-03-0
Molecular formula	Mixed triglycerides
Molecular weight	900 g/mol average
Structural formula	R_1-COO-CH_2 | R_2-COO-CH | R_3-COO-CH_2 Where R = alkyl chain from C16 to C22
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Products

Technical Product – Vegol TGAI

Property	Result
Colour and physical state	Light yellow liquid
Odour	Slight vegetable odour
Melting point	Not applicable
Boiling point or range	> 350°C

Property	Result
Density	0.91-0.93 g/mL
Vapour pressure	1.33×10^{-18} Pa
Ultraviolet (UV)-visible spectrum	$\lambda_{max} = 230$ nm
Solubility in water	Not soluble in water.
Solubility in organic solvents	Solvent — Solubility (g/L) 1,2-dichloroethane > 250 p-xylene > 250 ethylacetate > 250 n-heptane > 250 acetone > 250 methanol < 10
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} of 1,2,4-Trioctadec-9-en-oyl-glycerol was estimated at 23.2908 using the model HENRYWIN.
Dissociation constant (pK_a)	Not applicable
Stability (temperature)	May form haze at low temperatures (0-40°C)

End-Use Product – Vegol Insecticidal Oil, Ready-To-Spray

Property	Result
Colour	Pale yellow
Odour	Typical vegetable oil odour
Physical state	Liquid
Formulation type	Emulsifiable concentrate (EC)
Guarantee	96%
Container material and description	High density polyethylene bottles 1-1000 L
Density at 20°C	0.89-0.95 g/mL
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product was found to be stable when stored at 54°C for one month in plastic bottles.
Corrosion characteristics	No evidence of corrosion or deterioration was observed during the storage stability study.
Explodability	Not explosive as it does not contain any explosive ingredients.

End-Use Product – Vegol Commercial Insecticidal Oil

Property	Result
Colour	Pale yellow
Odour	Typical vegetable oil odour
Physical state	Liquid
Formulation type	Emulsifiable concentrate (EC)
Guarantee	96%
Container material and description	High density polyethylene bottles 1-1000 L
Density at 20°C	0.89-0.95 g/mL
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product was found to be stable when stored at 54°C for one month in plastic bottles.
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Property	Result
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Guarantee	96%
Container material and description	High density polyethylene bottles 1-1000 L
Density at 20°C	0.89-0.95 g/mL
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product was found to be stable when stored at 54°C for one month in plastic bottles.
Corrosion characteristics	No evidence of corrosion or deterioration was observed during the storage stability study.
Explodability	Not explosive as it does not contain any explosive ingredients.

1.3 Directions for Use

Vegol Commercial is a commercial class product, while Vegol Ready-to-Spray and Vegol Concentrate are domestic class products. All three products are for foliar application to the leaves, trunks, or stems of target plants and have both insecticidal/miticidal and fungicidal properties. The products are all applied at a 2% concentration, with a maximum of 2 dormant season and 4 summer applications, for control of mites, mealybugs, aphids, adelgids, whiteflies, psyllids (including pear psylla), scale, oak phylloxera, and grape phylloxera, and applied preventatively for suppression of various plant pathogen species that cause powdery mildew. Insect pests must be contacted with the spray. Host crops include a variety of fruits and vegetables; legumes; ornamental bedding plants, shrubs, and trees; fruit trees; berries; nuts; alfalfa; hops; and *Cannabis* (marihuana) produced commercially indoors for medical purposes. Applications can be made in both the greenhouse and outdoors. Additionally Vegol products control overwintering life stages, including eggs, of pests present in the dormant season (for example, scale insects, mites and mealybugs) on shrubs, evergreens, woody plants, fruit trees and shade trees.

1.4 Mode of Action

The main insecticidal/miticidal/fungicidal mode of action of canola oil is physical. The oil coats the insect or mite and floods their spiracles (breathing pores). This results in the rapid asphyxiation and suffocation of the organism. Canola oil is active against multiple life stages of the insect or mite, including eggs. It is not classified by either the Insecticide or the Fungicide Resistance Action Committees. As a fungicide, canola oil creates a physical barrier that prevents plant infection by fungi. There is also some evidence that canola oil reduces the production of spores by powdery mildew pathogens.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

No methods are required to quantify residues of canola oil due to its low toxicity and its history of use as a food additive (see Section 3.0 for additional details).

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Canola oil is produced in the canola plant. It is a mixture of esters (triglycerides of different fatty acids). The main fatty acids in canola oil are oleic, linoleic acid and linolenic acid. Fatty acids are an integral part of cell membranes of every living organism. They also occur as a food substrate in the form of their triglycerides (fats and oils). Linoleic and linolenic acid are essential fatty acids in the human diet. The source of the proposed canola oil technical grade active ingredient is certified food grade.

The human health toxicity studies reviewed for the registration of canola oil products indicate that the end-use products are expected to be of low toxicity by the oral, inhalation and dermal routes. Canola oil is not a skin sensitizer; however, it is considered to be minimally irritating to the eyes and mildly irritating to the skin. Consequently, the label will include protective measures to prevent irritation by requiring that anyone applying canola oil products must avoid contact with eyes, skin and clothing.

Canola oil is an edible substance that is readily metabolized by humans. Based on information in the published literature, canola oil is not a developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant. Furthermore, no adverse effects to the endocrine or immune systems are expected for canola oil.

Incident Reports

As of 3 February 2016, no human, domestic animal or environment incident reports involving canola oil had been submitted to the PMRA.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Dermal Absorption

No information was provided on the dermal absorption of canola oil. However, based on low dermal toxicity of canola oil, dermal absorption is not of concern.

3.2.2 Use Description

The end-use products are proposed for control of various insects and some fungal pathogens on food and ornamental crops indoors and outdoors. The proposed Vegol products are for commercial and domestic uses.

Vegol products are to be diluted to a 2.0% solution and applied using handheld trigger-sprayers, hand, hose or backpack sprayers. Treatment is to be repeated every 7–14 days if needed. A maximum of 6 applications per season are proposed.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

The proposed use of canola oil can result in exposure to workers during handling, mixing, loading and application of the product. Workers will be primarily exposed by dermal and inhalation routes and, to a lesser extent, the ocular route.

Risk from exposure to canola oil for mixers, loaders and applicators, as well as those responsible for clean-up, maintenance and repair activities, is not expected to be of concern due to the low toxicity of the active ingredient and reduced occupational exposure when label directions are followed.

3.2.4 Post-application Exposure and Risk

Post-application dermal exposure may occur when persons enter the treated sites soon after the application to handle treated foliage. Risk from dermal exposure is not of concern based on the low toxicity of canola oil.

3.2.5 Residential and Bystander Exposure and Risk

As the application of Vegol Commercial involves only authorized personnel, bystander exposure is expected to be minimal and not of concern when the end-use product is used according to the label directions, which include instructions for applicators to limit spray drift to neighbouring properties.

The proposed uses of the domestic class Vegol products will not result in exposure levels of concern. The domestic labels have adequate exposure mitigation measures to protect home users from the proposed uses. Post-application dermal exposure is possible when adults or children enter the treated site. Due to the low toxicity of canola oil and low exposure profile, risk to human health is not of concern.

3.3 Food Residue Exposure Assessment

3.3.1 Food

Based on low toxicity of canola oil and its history of dietary consumption as a food, no adverse effects are expected from the presence of residues on food.

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of canola oil from the proposed use in green house and outdoor crops in the general population and potentially sensitive subpopulations, including infants and children.

3.3.2 Drinking Water

Although the end-use products will not be applied near or directly to water, some drinking water exposure can occur through run-off from treated areas following rainfall. Exposure to canola oil in drinking water is expected to be minimal. In addition, toxicity to canola oil is low. Consequently, no risk due to exposure from drinking water is expected.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculations of acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for canola oil. Based on all the available information and hazard data, the PMRA concludes that canola oil is of low toxicity. Thus, there are no threshold effects of concern. As a result, there is no need to require definitive (multiple dose) testing or apply uncertainty factors to account for intra- and interspecies variability, safety factors or margins of exposure. Further factoring of consumption patterns amonginfants and children, special susceptibility in these subpopulations to the effects of canola oi , including neurological effects from pre- or postnatal exposures, and cumulative effects on infants and children of canola oil and other registered products containing canola oil, does not apply to this active ingredient.

As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of canola oil to human health.

3.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of canola oil to the general Canadian population, including infants and children, when the end-use products are used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.3.5 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Canola oil is of low toxicity and is a food ingredient with a long history of use. In addition, the source of the technical grade active ingredient is certified as food grade. Consequently, a MRL is not being specified under the PCPA for the proposed agricultural and greenhouse uses.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Canola oil is expected to rapidly transform in the environment (soil DT_{50} of 3 day, water DT_{50} of 7 days). When released in the environment it will partition to soil, stay with any eroded soil and will not mix significantly with most water bodies. It will mix in turbulant waters, but is expected to break down quickly. Residues on plants and soil are expected to transform rapidly. In aquatic environments, canola oil will either remain on the surface of the water or will associate with plants or suspended sediments until it is transformed by bacteria.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants.

Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (that is, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

Risk to most terrestrial organisms is expected to be minimal given the low toxicity reported for the species tested and the rapid transformation of canola oil in the environment (Table 2, Appendix I). Acute risk to beneficial arthropods such as parasitic wasps and predatory mites, may be of concern due to their small size and that if they are sprayed they could be susceptible to smothering and suffocation. Some effects on the fecundity of the predatory mite, *Typhlodromus pyri*, were also noted. The labels contain precautionary label statements to mitigate risks to beneficial predatory and parasitic arthropods. Bees are expected to be less susceptible to effects by the spray solution (in other words, suffocation caused by being coated with the spray solution) as they are larger, more robust insects than the beneficial arthropods that were tested. Therefore, bees are not expected to be at risk by the proposed uses of canola oil. Risk to birds and mammals is not expected as canola seed, canola seed meal, and canola oil are all used as food additives or sources for various birds and mammals when kept as livestock. Therefore, effects on wild birds and mammals are not expected. Risk to terrestrial plants was not identified at an application rate

of 25 g a.i./ha. The exposure due to spray drift reaching off-field terrestrial plants are expected to be similar to this rate for air blast, and lower for all other methods of application. Based on this, the non-toxic mode of action of canola oil, and the large scope of proposed uses on a wide variety of crops, risk to non-target terrestrial plants is not expected.

4.2.2 Risks to Aquatic Organisms

Risk was identified for *Daphnia magna* (Table 3, Appendix I) and this can be mitigated through the use of labeled buffer zones. Although no information was available to assess the effects to aquatic vascular plants, based on the non-toxic mode of action of canola oil, lack of effects on terrestrial vascular plants, and the wide variety of plants to be treated in the use pattern, risks to aquatic plants are not expected. A literature study conducted with treated sediment found canola oil to be slighly toxic to *Hyalella azteca*; however, when released to the environment, canola oil is not expected to reach the sediment before being broken down by bacteria. The proposed uses of canola oil are not expected to pose a risk of concern to other aquatic organisms (for example, algae, fish, amphibians, benthic organisms) as RQs did not exceed the LOC for these organisms.

5.0 Value

5.1 Consideration of Benefits

In the case of canola oil as an insecticide, resistance is unlikely to develop due to its physical mode of action. Canola oil itself is a new active ingredient; however, other mineral oils with similar modes of action are already registered for many of the canola oil uses. Despite this, canola oil is a new mode of action for use on several of the labelled vegetable and pulse crops as a summer spray, such as soybeans, asparagus, beets, and carrots, to control a variety of insect pests. As well, it is a new mode of action for use in the dormant season on members of the berry crop group. For both home owners and commercial users, these products are a new option to control several detrimental foliage feeding insect and mites. As well, canola oil has been identified in the Canadian Grower Priority Database as a priority for aphids, whiteflies, and psyllids in greenhouse vegetable production.

As a fungicide, resistance is also unlikely to develop due to its physical mode of action. Canola oil is a new fungicide active ingredient. Other oils are registered against powdery mildew on roses, ornamental trees, cucurbit vegetables, pome and stone fruits, berries, and grapes. No fungicidal oils are registered for use on hops or *Cannabis* (marihuana) produced commercially indoors for medical purposes. Furthermore, Canadian growers have identified the registration of fungicidal oils to manage powdery mildew on various crops as a priority. Canola oil will be an option for home owners and commercial users to suppress a very detrimental disease in several crops and plants.

5.2 Effectiveness Against Pests

Label claims against mites and insects were supported by a wide variety of information that included more than 20 laboratory bioassays and 25 field/greenhouse trials, published literature, scientific rationales, and additional information from state extension papers. Collectively, this information demonstrated that canola oil can be used as an effective tool to manage various life stages of aphids, mites, whiteflies, psyllids (including pear psylla), mealybugs, adelgids, grape phylloxera, oak phylloxera, and scales.

Label claims against powdery mildew were supported by four efficacy trials on different powdery mildew pathogens. The results were extrapolated to the other supported crops using scientific rationale based on pathogen/host similarities. The weight of evidence from the efficacy trials supported a claim against powdery mildew at the level of suppression on the target crops.

5.3 Non-Safety Adverse Effects

A number of trials evaluating non-safety adverse effects on a variety of hosts were conducted. Trials evaluating 2% canola oil showed no or slight phytotoxicity. On the labels, precautionary statements are present that recommend treatment of a small area before large scale application.

5.4 Supported Uses

The reviewed value information for canola oil was sufficient to support the claims. Details of the supported uses are located in Appendix 1, Table 4.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, canola oil was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Canola oil does not meet all Track 1 criteria, and is not considered a Track 1 substance.
- The technical product, Vegol TGAI, does not contain any impurities and is not expected to form any transformation products that meet all Track 1 criteria.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations, including DIR99-03[8] and DIR2006-02,[9] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Vegol TGAI does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The end-use products, Vegol Commercial, Vegol Ready-to-Spray and Vegol Concentrate, do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database considered for canola oil is sufficient to define the toxic effects that can result from exposure to this chemical. The technical product, Vegol TGAI and associated end-use products are expected to be of low acute toxicity via the oral, dermal, and inhalation routes. They are not considered to be dermal sensitizers, but are expected to be mildly irritating to the skin and minimal eye irritants and thus, the label will include protective measures to prevent irritation by requiring that anyone applying canola oil products must avoid contact with eyes, skin and clothing. Canola oil is not a developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1-Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

8 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

Loaders, mixers, applicators, and workers are not expected to be exposed to levels of canola oil that would be of concern to human health when canola oil is used according to label directions. Bystander and postapplication exposure is not of concern.

Dietary exposure to canola oil from the use of Vegol products is not of concern to human health when the products are used according to label instructions. PMRA did not specify an MRL under the *Pest Control Products Act* for canola oil.

7.2 Environmental Risk

Canola oil is expected to rapidly transform in the environment. In general, due to the quick breakdown of the canola oil, exposure to plants and animals will be limited. Acute risks to aquatic invertebrates and beneficial predatory and parasitic arthropods were identified, and precautionary label statements are required. Buffer zones to protect aquatic habitats (i.e., field spray, 2 m; air blast sprayer, 5 m) are also required. Canola oil is not expected to pose risks of concern to the environment when used according to the label.

7.3 Value

The value information provided to support the registration of products containing canola oil was in the form of efficacy trials, rationales, scientific literature, and crop production fact sheets. Efficacy of Vegol products against the insects and mites was acceptable. Vegol products will also provide suppression of powdery mildew on the labelled crops. Despite the presence of little to no phytotoxicity, statements are present on the label to address any potential adverse effects. Inclusion of canola oil in insecticide programs will provide Canadian growers with an additional end-use product option and, for some of the labeled pests, an alternative active ingredient with a mode of action that is different from those that are currently registered.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Vegol TGAI and Vegol Commercial, Vegol Ready-to-use and Vegol Concentrate, containing the technical grade active ingredient canola oil, to control a variety of insect and mite pests, as well as to suppress powdery mildew, on many ornamental, vegetable, fruit, and nut crops both in the field and greenhouse, as well as on *Cannabis* (marihuana) produced commercially indoors for medical purposes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
d	day(s)
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EC	emulsifiable concentrate
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
g	gram
h	hour(s)
ha	hectare(s)
kg	kilogram
K_{ow}	n–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LR_{50}	lethal rate 50%
MAS	maximum average score
mg	milligram
mL	millilitre
MRL	maximum residue limit
N/A	not applicable
nm	nanometre
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
RQ	risk quotient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
w/w	weight per weight dilution

Appendix I Tables and Figures

Table 1 Toxicity Profile of End – Use Products Containing Canola Oil

(Toxicity data requirements for the technical grade active ingredient have been waived based on canola oil's low toxicity profile).

Study Type/Animal/PMRA #	Study Results
Vegol products were not tested for acute oral, dermal, inhalation, skin irritation and eye irritation. Instead the applicant has requested that the results of toxicity studies performed on NEU1161 I, be used to support the registration decision for Vegol products.	
Acute oral toxicity/Rat/ PMRA#2510283	LD_{50} ♂ & ♀> 2000 mg/kg bw Low acute toxicity
Acute dermal toxicity/Rat/ PMRA#2510283	LD_{50} ♂ & ♀: > 2000 mg/kg bw Low dermal toxicity
Acute inhalation toxicity/Rat/ PMRA#2510283	LD_{50} ♂ & ♀:> 2.36 mg/L Low inhalation toxicity
Dermal irritation/ Rabbit/ PMRA#2510283	MAS = 2.3/8 (24, 48 and 72 hours) Mildly irritating
Eye irritation/Rabbit/ PMRA#2510283	MAS = 3.3/110 (1, 24, 48 and 72 hrs) Minimally irritating
A dermal sensitization study was conducted using NEU1160 I (alternate name for Vegol products).	
Dermal sensitization /Albino Guinea pig/ PMRA#2510284	Negative Canola oil is not a dermal sensitizer.

Table 2 Toxicity of Canola Oil to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Invertebrates					
Earthworm, *Eisenia foetida*	14 d Acute	NEU 1161 I (90% w/w a.i.)	LC_{50} >900 mg a.i./kg	N/A	2510327
Parasitic arthropod,	48 h Contact	NEU 1160 I (96% w/w a.i.)	LR_{50} = 88 kg a.i./ha	N/A	2510325

Aphidius rhopalosiphia					
Predatory arthropod, *Typhlodromus pyri*	7 d Contact ǂ and Fecundity	NEU1162 I (96% w/w a.i.)	LR_{50} > 27 kg a.i./ha; significant effects on fecundity# at application rates ≥9 kg a.i./ha	N/A	2510326
Terrestrial vascular plants: Dicots - *Raphanus sativus, Cucumis staivus, Vicia faba, Lycopersicon esculentum;* Monocots - *Allium cepa, Avena sativa*	21 d Vegetative Vigour; Limit test at 25 kg a.i./ha	NEU1161 I (nominal pyrethrine 4.59 g/L; canola oil 825.3 g/L)	No observed effects on mortality or fresh weight.	N/A	2510329
Freshwater species					
Daphnia magna	48 h Acute	Canola oil	EC_{50} = 3.4 mg a.i./L (mortality/immobility)	Moderately toxic	2509293
Rainbow trout	96 h Acute	Canola oil	LC_{50} >249.4 mg a.i./L	Practically non-toxic	2509294
Freshwater alga, *Scenedesmus subspicatus*	72 d Acute	Canola oil	EC_{50} = 82.2 mg a.i./L	Slightly toxic	2509295
Hyalella azteca	14 d Acute	Canola oil	EC_{50} ~ 17.5 g canola oil/kg sediment	Slightly toxic	Study from literature

N/A = not applicable
ǂ Contact exposure via dried residues on plant leaves.
Mean number of eggs per female.

Table 3 Screening Level Risk Assessment on Non-target Species

Organism	Exposure	Endpoint value	Uncertainty Factor (UF)	EECǂ	RQ#	LOC Exceeded##
Terrestrial Invertebrates						
Earthworm	Acute	>450 mg a.i./kg soil	2	20.1 mg a.i./ kg soil	<0.04	No
Predatory arthropod	Contact	88 kg a.i./ha	1	87.3 kg a.i./ha	1.0	No

Freshwater species						
Daphnia magna	Acute	1.7 mg a.i./L	2	8.86 mg a.i./L	5.2	Yes
Rainbow trout	Acute	>24.9 mg a.i./L	10	8.86 mg a.i./L	<0.4	No
Freshwater alga	Acute	41.1 mg a.i./L	2	8.86 mg a.i./L	0.2	No
Amphibians	Acute	>249 mg a.i./L	1	47.27 mg a.i./L	<0.19	No
Hyalella azteca	Acute	8750 mg a.i./kg sediment	2	20.1 mg a.i./kg soil**	0.002	No

‡Estimated Environmental Concentration (EEC) calculations:
Cumulative rate was used, based on 6 applications of 36.1 kg a.i./ha. For soil, a DT_{50} of 3 days, 15 cm of soil and a bulk density of 1.5 g/cm^3 were used to give an EEC of 20.1 mg a.i./kg soil. For water, a DT_{50} of 7 days was used and an 80 cm water body giving an EEC of 8.86 mg a.i./L. A 15 cm water body for amphibians gives an EEC of 47.27 mg a.i./L. A foliar dissipation half-life of 10 days gives an EEC of 87.3 kg a.i./ha for predatory arthropods.

Risk Quotient (RQ) = EEC ÷ (toxicity endpoint/UF)

Level of Concern, LOC = 2 for predatory and parasitic arthropods; 1 for all other organisms tested.

**No sediment calculations could be determined, thus soil values were used instead. This is expected to be overly conservative.

Table 4 List of Supported Uses

Crop	Pest	Application Timing	Rate
Greenhouse and outdoors: Flowering, foliage and bedding plants	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Roses	aphids, mealybugs, mites, scales, whiteflies	Dormant and summer application Begin when pests appear - repeat every 7 to 14 days as needed	2%
	powdery mildew (suppression) (*Podosphaera pannosa)*	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%
Ornamental and shade trees (flower and foliage plants, ash, birch, barberry, flowering cherry, crabapples, dogwood, elm, evergreens, hawthorn, holly, lilac,	aphids, adelgids, mealybugs, mites, psyllids, scales, whiteflies, oak phylloxera	Dormant, pre-bloom and summer application Begin when pests appear - repeat every 7 to 14 days as needed	2%

magnolia, maple, oak, pine, flowering peach, flowering plum, privet, pyracantha, spruce, sycamores, tuliptree, willow), ornamental shrubs			
Flowering cherry, crabapples, hawthorn, flowering peach, flowering plum and pyracantha	powdery mildew (suppression) (*Podosphaera clandestina*)	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%
Houseplants	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Greenhouse and outdoors: Beets, carrots, potatoes, radishes, rutabagas, sugar beets, turnips	aphids, scales, mealybugs, mites, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Onions - greenhouse and outdoors	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Greenhouse and outdoors: Lettuce, celery, chard	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Greenhouse and outdoors: Broccoli, cabbage, cauliflower, kale	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Greenhouse and outdoors: Soybeans, beans, peas	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Crop Group 8-09, Fruiting Vegetables (greenhouse and outdoors)	aphids, mealybugs, mites, psyllids, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Crop Group 9, Cucurbit Vegetables (greenhouse and outdoors)	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
	powdery mildew (suppression) (*Podosphaera xanthii)*	Initiate sprays when conditions are favourable for disease development or when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is	2%

		recommended under moderate to high disease pressure.	
Asparagus	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Apples, pears	aphids, scales, mites, pear psylla	Dormant to green tip and summer application. Avoid application during bloom. Begin when pests appear - repeat every 7 to 14 days as needed	2%
	powdery mildew (suppression) (*Podosphaera leucotricha)*	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%
Apricots, cherries, nectarines, peaches, plums, prunes, sour cherry	aphids, scales, mites,	Dormant to pre-bloom and summer application Begin when pests appear - repeat every 7 to 14 days as needed	2%
	powdery mildew (*Podosphaera clandestina, Podosphaera pannosa)*	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%
Note: On peaches use only one dormant application per season. Certain varieties of plums and prunes may be injured by oil sprays. Do not apply to oil sensitive varieties. Do not apply to trees lacking moisture.			
Crop Group 13-07: Berries (greenhouse and outdoor)	aphids, grape phylloxera, mealybugs, mites, scales	Dormant and summer application Begin when pests appear - repeat every 7 to 14 days as needed	2%
Greenhouse and outdoors: Blackberry, buffaloberry, cloudberry, currant, elderberry, gooseberry, jostaberry, juneberry, raspberry, strawberry, grape	powdery mildew (suppression) *(Podosphaera spp., Uncinula necator)*	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%

Hazelnuts, chestnuts, pecans, walnuts	aphids, scales, mites	Dormant to pre-bloom and summer application Begin when pests appear - repeat every 7 to 14 days as needed	2%
Corn	aphids, mealybugs, mites, scales, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Alfalfa (animal feed)*	spider mites	Begin when pests appear - repeat every 7 to 14 days as needed	2%
Hops	powdery mildew (suppression) (*Podosphaera macularis*)	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%
Cannabis (marihuana) – produced commercially indoors for medical purposes *	aphids, mites, whiteflies	Begin when pests appear - repeat every 7 to 14 days as needed	2%
	powdery mildew (suppression) (*Podosphaera macularis*)	Initiate sprays when disease first appears. Continue sprays every 7-14 days. The 7 day application interval is recommended under moderate to high disease pressure.	2%

* Vegol Commercial (commercial class) only

Table 5 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
Toxic or toxic equivalent according to the *Canadian Environmental Protection Act*[1]	Yes		Yes	Not applicable
Predominantly anthropogenic[2]	Yes		No	
Persistence[3]:	Soil	Half-life ≥ 182 days	3 days	
	Water	Half-life ≥ 182 days	7 days	
	Sediment	Half-life	Expected to be similar to	

		≥ 365 days	soil	
	Air	Half-life ≥ 2 days or evidence of long range transport	Not relevant	
Bioaccumulation[4]	Log K_{ow} ≥ 5		1.3	
	Bioconcentration factor ≥ 5000		not available	
	Bioaccumulation factor ≥ 5000		not available	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).
[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) then the criterion for persistence is considered to be met.
[4] Field data (for example, bioaccumulation factors) are preferred over laboratory data (for example, bioconcentration factors) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2509268	2015, Binder 1, DACO: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1, 2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.1 4.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3 .1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2509269	2015, Spectrum Canola Oil Process, DACO: 2.11.3 CBI
2509270	2015, IUPAC, Gas-liquid chromatography of fatty acid methyl esters, DACO: 2.13.1 CBI
2509271	2015, IUPAC, Preparation of the fatty acid methyl esters, DACO: 2.13.1 CBI
2509272	2013, COA Canola Oil, DACO: 2.13.3 CBI
2509273	2014, COA Canola Oil - 2, DACO: 2.13.3 CBI
2509274	2015, Canola Oil: Physical and Chemical Properties, DACO: 2.14.13,2.14.14
2509275	2015, Canola Oil: Physical and Chemical Properties (2), DACO: 2.14.13, 2.14.14
2509276	1999. US EPA, US EPA Canola Oil RED, DACO: 2.16,4.1,8.1,9.1
2510277	2015, Binder 1, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.3.1, 3.4,3.4.1,3.4.2,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5. 4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2510278	2001, Storage Stability of NEU1160, DACO: 3.5.10 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2510283	2015, Binder 2, DACO: 4.1, 4.6, 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, 4.6.6
2510284	2002, Assessment of Contact Hypersensitivity to NEU1160 I in the Albino guinea Pig, DACO: 4.6.6
2510285	2015, Binder 3, DACO: 5.1, 5.10, 5.11, 5.13, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
2510286	2012, OECD Registration Report, Part B, Section 3: Mammalian Toxicology, DACO: 5.1
2510317	US EPA, 1998, Canola Oil; Exemption from the Requirement of a Tolerance, DACO: 7.1

3.0 Environment

PMRA Document Number	Reference
2509268	2015, Binder 1, DACO: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1, 2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14. 14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3.1,2 .4,2.5,2.6,2.7,2.8,2.9 CBI
2509269	2015, Spectrum Canola Oil Process, DACO: 2.11.3 CBI
2509270	2015, Gas-liquid chromatography of fatty acid methyl esters, DACO: 2.13.1 CBI
2509271	2015, Preparation of the fatty acid methyl esters, DACO: 2.13.1 CBI
2509272	2013, COA Canola Oil, DACO: 2.13.3 CBI
2509273	2014, COA Canola Oil - 2, DACO: 2.13.3 CBI
2509274	Canola Council of Canada, 2015, Canola Oil: Physical and Chemical Properties, DACO: 2.14.13,2.14.14
2509275	Canola Council of Canada, 2015, Canola Oil: Physical and Chemical Properties (2), DACO: 2.14.13,2.14.14
2509276	1999, USEPA Canola Oil RED, DACO: 2.16,4.1,8.1,9.1
2509288	2015, Binder 2, DACO: 12.7,2.0,4.1,7.1,8.1,9.1 CBI
2509291	2005, OECD Annex II, Section 5, Point 7: Fate and behavious in the environment, DACO: 8.1
2509292	2005, OECD Annex II, Section 6, Point 8: Ecotoxicological Studies, DACO: 9.1
2509293	2000, Assessment of Toxic Effects of Rubol/Rapson on Daphnia magna using the 48h Acute Immobilisation Test, DACO: 9.3.2
2509294	2000, Acute Toxicity Testing of Rubol/Rapsol in Rainbow Trout (Oncorhynchus mykiss), DACO: 9.5.2.1
2509295	2000, Testing of Toxic Effects of Rubol/Rapsol on the Single Cell Green Alga Scenedesmus subspicatus, DACO: 9.8.2
2510320	1999, The biodegradability and microbial toxicity testing of lubricants - some recommendations, DACO: 8.1
2510321	1992, A Correlation Between the Biodegradability of Oil Products in the CEC L-33-T-82 and Modified Sturm Tests, DACO: 8.1
2510322	1994, The Interpretation of the CEC L-33-T-82 Biodegradability Test Data, DACO: 8.1
2510323	2012, Registration Report Part B, Section 6: Ecotoxicological Studies, DACO: 9.1
2510324	2002, Acute Toxicity of NEU1160I to Daphnia Magna in a 48-hour Immobilization Test, DACO: 9.1,9.3.2
2510325	2002, A rate-response extended laboratory test to determine the effects of NEU1160I on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae), DACO: 9.1,9.2.6
2510326	2002, A rate-response extended laboratory test to determine the effects of Neu 116- I on the predatory mite, Typhlodromus pyri (Acari:Phytoseiidae), DACO: 9.1,9.2.5
2510327	1998, Acute Toxicity of NEU 1161 I on Earthworms, Eisenia foetida Using an Artificial Soil Test, DACO: 9.1,9.2.3.1

2510328 1998, Assessment of the Side Effects of NEU1161I on the activity of the Soil Microflora, DACO: 9.1

2510329 2001, Effects of NEU1161I on Terrestrial (Non-Target) Plants: Vegetative Vigour Test, DACO: 9.1,9.8.4

2510330 2012, Diet of nestling Linnets Carduelis cannabina on lowland farmland before and after agricultural intensification: Capsule between the 1960s and 1990s, nestling diet has changed in ways consistent with the impact of agricultural intensification on the availability of seed sources, DACO: 9.1,9.6.1

4.0 Value

PMRA Document Number	Reference
2510287	2015, Binder 4, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2, 10.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4
2510288	2015, Efficacy Summaries, DACO: 10.2.3.1
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